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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 557,262	04 24 2000	Robert D. Rosenberg	MIT-087	8522

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/557,262

Applicant(s)

ROSENBERG ET AL.

Examiner

Ram Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 61-76 is/are pending in the application.
- 4a) Of the above claim(s) 13-28 and 33-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 61-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: *detailed action*

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DETAILED ACTION

1. Response and amendment filed 5-8-02 has been received.
2. Claims 1-12 and 29-32 have been cancelled.
3. New claims 61-76 have been entered.
4. Claims 1-60 are pending in the instant application.
5. Claims 13-28 and 33-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.
6. Claims 61-76 pertaining to human and murine 3-OST-1 are instantly under investigation.

Oath/Declaration

7. The oath or declaration is defective as noted in the previous office action of 11-8-01.

Applicants' response that a substitute declaration will be filed is acknowledged.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: (i) an isolated nucleic acid that encodes a human or mouse 3-OST-1 protein, wherein said isolated nucleic acid comprises the nucleotide sequence of SEQ ID NO 1 or SEQ ID NO 3 and wherein said isolated

nucleic acid encodes the protein disclosed in SEQ ID NO 2 and SEQ ID NO 4 respectively (ii) an isolated nucleic acid that encodes a 3-O-sulfotransferase domain of the human or mouse 3-OST-1 protein wherein the domain consists of residue 53-311 or 21-307 of SEQ ID NO 2 or residue 49-307 or 21-303 of SEQ ID NO 4 and wherein said human or mouse 3-OST-1 protein has sequence specific HS-binding activity and (iii) an isolated host cell selected from the group consisting of: bacterial cells, yeast cells, insect cells, and mammalian cells, wherein the mammalian cells are selected from the group consisting of: COS-7 cells, CHO, murine primary cardiac microvasculature endothelial cells, murine mast cell line C57.1, human primary endothelial cells or umbilical vein, F9 embryonal carcinoma cells, rat fat pad endothelial cells, and L cells, wherein the isolated host cell comprises the nucleic acid, does not reasonably provide enablement for any other embodiments encompassed by the claimed invention, for reasons of record set forth in the previous office action of 11-8-01. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that while new claims 61-64, 66, 67, and 69-71 are based on the office action of 11-8-01, other claims have broader scope than what was indicated in the office action. It is noted that the scope rejection of the claims indicated to be enabled in the previous office action has been modified in view of further consideration since the enabled scope of the invention encompassed any variants of human or mouse 3-OST-1, however, the specification as filed is not enabling for any variants of 3-OST-1 as discussed in the previous office action of 11-8-01. Furthermore, applicants have not amended claims 73-76 that the cells are isolated host cells.

The invention as claimed encompasses any nucleic acids that encodes a 3-OST-1 protein, that has a 3'-O-sulfotransferase domain of a 3-OST-1 protein and t could be a human protein or mouse protein, proteins that have a 250-276 aa of SEQ ID NO 2 or 246-272 of SEQ ID NO 4 or other fragments of SEQ ID NO 2 and have specific HS binding affinity. Claims are also directed to nucleic acids that have 85% sequence identity to SEQ ID NO 1. When given the broadest interpretations,

claims 61-63 would encompass any allelic variants of nucleic acids encoding human or mouse or any 3-OST-1 proteins. As noted in the previous office action of 11-8-01, the specification as filed does not provide sufficient guidance as to how an artisan of skill would have made and used the claimed invention commensurate with the scope of the claims. An artisan of skill would have required extensive experimentation to practice the claimed invention commensurate with the scope of the claims and such experimentations would have been considered because the art of making and using the claimed invention was unpredictable at the time of the invention and the experimentation required would not have been routine, as discussed below. It is noted that applicants have not discussed any of the issues of rejections set forth in the previous office action of 11-8-01 except for canceling previous claims and filing new claims.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 68 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 68 is vague and indefinite because it is unclear as to what is meant by the phrase "wherein the nucleic acid comprises a nucleotide sequence encoding residues 250-276 of SEQ ID NO 2 encoding a functional fragment". It seems like "and" is missing between "encoding" and "a functional fragment".

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claim 61, 73 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al (EST database accession no. AA041885, 9-3-96).

Marra et al teach a nucleic acid that has 100% sequence similarity and 96.296% sequence identity with the nucleotide sequence that would encode aa 246-272 of SEQ ID NO 4. Marra et al note that the nucleic acid encodes a glycosaminoglycan N-acetylglucosaminyl N-deacetylase. While the art does not call the nucleic acid 3-OST1, since it would encode the amino acid sequence, it would have the activity as recited. The art also teaches that the nucleic acid was isolated from murine library and since the plasmid comprising the nucleic acid was grown, it would encompass the claim 74.

Accordingly, the nucleic acid of Marra et al anticipates the nucleic acid of claims 61, 73 and 74.

14. Claim 61, 68, 73 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al (EST database accession no. W62484, 6-7-96).

Marra et al teach a nucleic acid that has 100% sequence similarity and identity with the nucleotide sequence that would encode aa 250-276 of SEQ ID NO 2. Marra et al note that the nucleic acid encodes a glycosaminoglycan N-acetylglucosaminyl N-deacetylase. While the art does not call the nucleic acid 3-OST1, since it would encode the amino acid sequence, it would have the activity as recited. The art also teaches that the nucleic acid was isolated from murine library and since the plasmid comprising the nucleic acid was grown, it would encompass the claim 74.

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Accordingly, the nucleic acid of Marra et al anticipates the nucleic acid of claims 61, 68, 73, and 74.


15. No claim is allowed.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.


RAM R. SHUKLA, PH.D.
PATENT EXAMINER